K043551

FEB 1 8 2005

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5 PSM Module, (consisting of E-PSM and E-PSMP modules) and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

December 21, 2004

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5 PSM Module, (consisting of E-PSM and E-PSMP modules) and accessories

COMMON NAME:

Multiparameter Hemodynamic Module

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

MHX	Monitor, Physiological,Patient (With Arrhythmia Detection or Alarm)	870.1025
MLD	Monitor, ST segment with Alarm	870.1025
DSK	Blood pressure computer	870.1110
DRQ	Transducer signal amplifier and conditioner	870.2060
DQA	Oximeter	870.2700
DPZ	Ear Oximeter	870.2710
DRT	Cardiac Monitor (including cardiotachometer and rate alarm)	870.2300
DPS	Electrocardiograph	870.2340
DXN	Non-invasive blood pressure measurement system	870.1130
FLL	Clinical Electronic Thermometer	880.2910

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5 PSM Module, (consisting of E-PSM and E-PSMP modules) and accessoriesis substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-PRESTN..01 Module (K041772)

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda S/5 PSM Module, (consisting of E-PSM and E-PSMP modules) and accessories is a hemodynamic multiparameter module which is able to measure ECG, two Invasive blood pressures, SpO2, two Temperatures, Non-invasive blood pressure and Impedance Respiration. The intended use for the modified device is the same as the predicate, Datex-Ohmeda M-PRESTN..01 module and accessories (K041772). The indications for use are also the same. There has been no change to the basic technology from the predicate. The Datex-Ohmeda PSM module (model family E-PSM(P)) and accessories is a hemodynamic multiparameter module which is able to measure ECG, two Invasive blood pressures, SpO2, two Temperatures, Non-invasive blood pressure and Impedance Respiration. The Datex-Ohmeda E-PSM(P) module can be used with the Datex-Ohmeda S/5 FM Monitor, with main software S/5 FM with L-FICU04..00 and L-FICU04A..00 which has a separate 510(k).
There are 2 different model variants of the module:
E-PSMP: (includes all possible parameters) NIBP, ECG, SpO2, 2*T, 2*inv. press.,Resp
E-PSM: (does not include invasive pressures) NIBP, ECG, SpO2, 2*T, Resp.

E-PSMP is a hemodynamic plug-in parameter module including the NIBP measurement, 12-lead ECG with the Impedance Respiration measurement, SpO2 with the plethysmographic waveform, two invasive pressure measurements (P1 and P2) and two temperature measurements (T1 and T2). E-PSMP is a hemodynamic measuring module for a modular monitoring system.This module can be used in the FM modular monitor.
The monitor displays waveforms and measurement readings, and handles the trending and alarm management. The ECG (e.g. heart beat and arrhythmia detection) and the Impedance Respiration algorithms are in the monitor software. The modules measure signals and send them to the monitor. The NIBP, SpO2, Temperature and Invasive Pressure algorithms are in the module. There are two available options of the module: E-PSMP with invasive pressures P1 and P2 and E-PSM without P1 and P2. There are three parameter circuit boards inside the E-PSMP module for processing the measurement signals. Each processing board has a microcontroller with software.

INTENDED USE as required by 807.92(a)(5)

Intended use:
The Datex-Ohmeda S/5 PSM Module, (consisting of E-PSM and E-PSMP modules) and accessories is intended for monitoring hemodynamic parameters of hospitalized patients.

Indications for use:
The Datex-Ohmeda S/5 PSM Module, (consisting of E-PSM and E-PSMP modules) and accessories are indicated for monitoring of hemodynamic parameters of all hospital patients. The hemodynamic parameters of the module comprise ECG (including ST-segment and arrhythmia), Impedance respiration, NIBP, Temperature, SpO2 (including monitoring during conditions of clinical patient motion), and invasive blood pressure.
Impedance Respiration measurement is indicated for patients ages 3 and up..
The NIBP measurement is indicated for patients who weigh 5kg (11 lbs.) and up..
The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda E-PSM Module is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-PRESTN..01 Module (K041772). The E-PSMP module has the following similarities compared to the predicate M-PRESTN..01 (K041772):

§ identical intended use and indications for use
§ identical fundamental scientific technology
§ use the same operating principle
§ identical ECG connector
§ identical arrhythmia and ST analysis
§ have the same safety and effectiveness
§ have the same user interface at the monitor and alarms
§ are manufactured using the same processes

The main differences between the new E-PSMP and the predicate M-PRESTN..01 (K041772) is primarily due to fact that the new E-PSM module has the following changes:

§ new shape and size and thus differing mechanics
§ new GE-type NIBP, invBP, Temperature and SpO2 module connectors
§ dynamic module addressing in the module-to-monitor communication

Based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of Datex-Ohmeda E-PSMP Module are substantially equivalent to the predicate Datex-Ohmeda M-PRESTN..01 Module (K041772).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

Datex-Ohmeda S/5 E-PSMP and E-PSM Module and accessories complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested through validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- FDA regulation 21 CFR 898.12
- IEC 60601-1:1988 + Amendments: A1:1991, ,A2:1995,
- IEC 60601-1-2:2001
- IEC 60601-1-4:1996 + A1 1999
- ANSI/AAMI ES1 (1993)
- CAN/CSA C22.2 No. 601-1-M90 + S1 (1994)+Amdt2:1998
- IEC 60601-2-27 (1994)
- IEC 60601-2-30 (1999)
- IEC 60601-2-34 (2000)
- IEC 60601-2-49:2001
- EN 12470-4:2000
- ISO 9919 (1994) / EN 865:1997
- UL 2601-1 : 1997

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5 E-PSMP and E-PSM Module and accessories as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Datex Ohmeda
c/o Mr. Joel Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K043551
Trade Name: Datex-Ohmeda S/5 PSM Module, (consisting of E-PSM and E-PSMP modules) and accessories
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)
Regulatory Class: II (two)
Product Code: MHX
Dated: December 22, 2005
Received: December 23 2005

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043551

Indications for Use

510(k) Number (if known): K043551

Device Name: Datex-Ohmeda S/5 PSM Module, (consisting of E-PSM and E-PSMP modules) and accessories

Indications for Use:

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Impedance Respiration measurement is indicated for patients ages 3 and up.

The NIBP measurement is indicated for patients who weigh 5kg (11 lb.) and up.

The device is indicated for use by qualified medical personnel only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043551